

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 18 April 2000 (18.04.00)	
International application No. PCT/EP99/05989	Applicant's or agent's file reference KP/BM45330
International filing date (day/month/year) 13 August 1999 (13.08.99)	Priority date (day/month/year) 18 August 1998 (18.08.98)
Applicant THONNARD, Joelle	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

11 February 2000 (11.02.00)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer C. Villet Telephone No.: (41-22) 338.83.38
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Form PCT/IB/331 (July 1992)

EP9905989

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 00/00425

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C12N15/31 C07K14/22 C07K16/12 G01N33/68 A61K39/095 A61K39/40 A61K31/70		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 C12N C07K		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	W. PAN ET AL: "Regulation of the permeability of the gonococcal cell envelope by the mtr system" MOLECULAR MICROBIOLOGY, vol. 11, no. 4, 1994, pages 769-775, XP000907174 the whole document	1,2
A	especially fig.2 page 771	3-10
X	D.C. MARCHION ET AL: "Generation of antiserum to specific epitopes" MOLECULAR BIOTECHNOLOGY, vol. 6, 1996, pages 231-240, XP000910676 the whole document	1,2,5, 11,14, 16-18
-/-		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "A" document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
19 May 2000		06/06/2000
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Le Cornec, N

INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 00/00425

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	K.E. HAGMAN ET AL: "Resistance of <i>Neisseria gonorrhoeae</i> to antimicrobial hydrophobic agents is modulated by the mtrRCDE efflux system" MICROBIOLOGY, vol. 141, no. part3, March 1995 (1995-03), pages 611-622, XP000907176 the whole document	1,2
A	-----	3-10
A	J.R. FARIBORZ ET AL: "Rifampin resistance in <i>Neisseria meningitidis</i> due to alterations in membrane permeability" ANTIMICROBIAL AGENTS AND CHEMOTHERAPY, vol. 40, no. 3, March 1996 (1996-03), pages 646-651, XP000907188 page 647, right-hand column -page 648, left-hand column; figures 1,4 -----	1-10
A	C.E. ROUQUETTE ET AL: " <i>Neisseria meningitidis</i> contains IS elements within the mtr operon" ABSTRACTS OF THE GENERAL MEETING OF THE AMERICAN SOCIETY FOR MICROBIOLOGY., vol. 97, 4 - 8 May 1997, page 60 XP002138146 AMERICAN SOCIETY FOR MICROBIOLOGY, WASHINGTON., US ISSN: 0067-2777 abstract B-181 -----	1-10
A	EP 0 467 714 A (MERCK & CO INC) 22 January 1992 (1992-01-22) the whole document -----	1-18
A	EP 0 301 992 A (NACIONAL DE BIOPREPARADOS CENT) 1 February 1989 (1989-02-01) abstract; claims -----	1-18
A	WO 98 02547 A (INST NAT SANTE RECH MED ;MAX PLANCK GESELLSCHAFT (DE); SMITHKLINE) 22 January 1998 (1998-01-22) abstract; claims -----	1-18

INTERNATIONAL SEARCH REPORT

Information on patent family members



I. International Application No

PCT/EP 00/00425

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0467714 A	22-01-1992	AU 8114091 A	23-01-1992
		CA 2047043 A	20-01-1992
		FI 913473 A	20-01-1992
		JP 6056690 A	01-03-1994
		MX 9100272 A	28-02-1992
		NO 912822 A	20-01-1992
		PT 98381 A	29-05-1992
		ZA 9105629 A	25-03-1992
		AU 8113691 A	23-01-1992
		CA 2050635 A	20-01-1992
		FI 913475 A	20-01-1992
		JP 6016569 A	25-01-1994
		JP 6055679 B	27-07-1994
		NO 912823 A	20-01-1992
		NZ 238974 A	23-12-1992
		PT 98382 A	29-05-1992
		ZA 9105627 A	25-03-1992
		AU 8113791 A	23-01-1992
		CA 2047030 A	20-01-1992
		FI 913474 A	20-01-1992
		JP 6041197 A	15-02-1994
		MX 9100274 A	28-02-1992
		NO 912824 A	20-01-1992
		PT 98383 A	30-06-1992
		ZA 9105628 A	25-03-1992
EP 0301992 A	01-02-1989	AT 122893 T	15-06-1995
		AU 615461 B	03-10-1991
		AU 2031288 A	25-05-1989
		AU 5319794 A	24-03-1994
		AU 706213 B	10-06-1999
		AU 7422696 A	20-02-1997
		AU 8134991 A	31-10-1991
		DE 3853854 D	29-06-1995
		DE 3853854 T	08-02-1996
		ES 2074445 T	16-09-1995
		GR 3017218 T	30-11-1995
		IN 167607 A	24-11-1990
		JP 1125328 A	17-05-1989
		RU 2023448 C	30-11-1994
		US 5597572 A	28-01-1997
WO 9802547 A	22-01-1998	US 5747653 A	05-05-1998
		FR 2751000 A	16-01-1998
		AU 3697797 A	09-02-1998
		EP 0951552 A	27-10-1999

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference KLP/BM45330	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP99/05989	International filing date (day/month/year) 13/08/1999	Priority date (day/month/year) 18/08/1998
International Patent Classification (IPC) or national classification and IPC C12N15/31		
Applicant SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicabilityIV <input type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input checked="" type="checkbox"/> Certain documents citedVII <input type="checkbox"/> Certain defects in the international applicationVIII <input checked="" type="checkbox"/> Certain observations on the international application		
Date of submission of the demand 11/02/2000	Date of completion of this report 21.03.2000	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Bretherick, J Telephone No. +49 89 2399 8415 	

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/05989

I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-58 as originally filed

Claims, No.:

1-26 as originally filed

Drawings, sheets:

1/17-17/17 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

see separate sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/05989

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-28
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-28
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-28
	No:	Claims	

2. Citations and explanations

see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP99/05989

1. **Re. Part I**, the application also comprises a 20-page sequence listing.
2. This International Preliminary Examination Report is written on the assumption that the entire claimed subject-matter of the application enjoys valid priority rights.

The only directly related document is WO99/24578, filing date 9/10/1998, published 20/05/1999, with earliest priority date of 6/11/97 (GB 9723516.2). Were the priority not valid then this document would disclose art sequences with significant similarities and uses to the currently claimed subject-matter.

This document is also cited under R. 70.10 PCT (**Re. Part VI**).

3. Regarding novelty and inventive step, (**Part V, Art. 33(1)(2)(3) PCT**), the claimed polypeptide sequences of the *N. meningitidis* BASB024 gene has no significant identity at the desired level indicated in the claims to any known art sequence. The sequences have been obtained utilising a non-public database which contains partial genomic sequences from ***N. meningitidis*** Serogroup B strain ATCC 13090 and show 24% identity in an 837 amino acids overlap to *Serratia marcescens* HasR haem acquisition outer membrane protein.

This polypeptide enables the identification of antibodies in the sera of convalescent individuals who have been diagnosed as having suffered from a meningococcal infection.

Since there is no significant homology in the available art, the subject-matter, relating to the claimed sequences, their encoding nucleotide sequences and their respective uses in diagnosis and therapy and/or vaccination are novel and involve an inventive step.

4. **Regarding Part VIII, Art. 5 PCT:**

Whilst the diagnostic potential of the embodiments of polypeptide and/or polynucleotide have been documented in the application, there are no actual results showing that the formulations including the claimed polypeptides and/or encoding polynucleotides might actually have a therapeutic effect, for example as

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP99/05989

a vaccination. There is no data indicating what dosage would be effective at bringing this effect about. Claims 21-23 and 26-28 lack adequate support under Art. 6 PCT and, in view of the lack of real data available are considered to be deficient under Art. 5 PCT.

PATENT COOPERATION TREATY

RECEIVED

24 MAR 2000

NEW HORIZONS COURT

PCT

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

GIDDINGS, Peter John
SMITHKLINE BEECHAM PLC
Corporate Intellectual Property
Two New Horizons Court
Brentford
Middlesex TW8 9EP
GRANDE BRETAGNE

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Rule 71.1)

Date of mailing (day/month/year)	21.03.2000
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Applicant's or agent's file reference KLP/BM45330	IMPORTANT NOTIFICATION
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International application No. PCT/EP99/05989	International filing date (day/month/year) 13/08/1999	Priority date (day/month/year) 18/08/1998
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Applicant

SMITHKLINE BEECHAM BIOLOGICALS S.A. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/ European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Vullo. C Tel. +49 89 2399-8061
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference KLP/BM45330	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP99/05989	International filing date (day/month/year) 13/08/1999	Priority date (day/month/year) 18/08/1998
International Patent Classification (IPC) or national classification and IPC C12N15/31		
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3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 11/02/2000	Date of completion of this report 21.03.2000
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Bretherick, J Telephone No. +49 89 2399 8415 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/EP99/05989

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☐ the drawings, sheets:

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4. Additional observations, if necessary:

see separate sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/05989

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-28
	No:	Claims	
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	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-28
	No:	Claims	

2. Citations and explanations

see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

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see separate sheet

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**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/EP99/05989

a vaccination. There is no data indicating what dosage would be effective at bringing this effect about. Claims 21-23 and 26-28 lack adequate support under Art. 6 PCT and, in view of the lack of real data available are considered to be deficient under Art. 5 PCT.